IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Anthony H. Cincotta et al.

Application No.: 10/719,534 Confirmation No.: 3460

Filed: November 21, 2003 Art Unit: 1642

For: **GROWTH INHIBITION AND ERADICATION OF SOLID TUMORS USING NEUROENDOCRINE RESETTING THERAPY AND PHOTODYNAMIC THERAPY** Examiner: S. E. Aeder

RESPONSE TO ELECTION OF SPECIES REQUIREMENT

MS Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

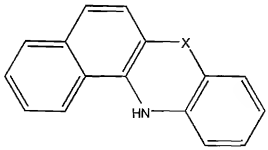
Dear Sir:

This paper responds to the Office Action for the above-identified application that was mailed May 26, 2006. This Response is accompanied by payment to extend the time to reply to November 26, 2006. Because November 26 was a Sunday, the time for response is further extended to November 27, 2006. The Director is hereby authorized to charge any additional fees which may be required, or credit any overpayment, to Deposit Account Number 04-0100.

The aforementioned Office Action sets forth an election/restriction requirement in which the Examiner requires election of a species of prolactin enhancer and further requires election of a species of photosensitizer. In response, Applicants elect domperidone as a species of prolactin enhancer and elect as a photosensitizer 5-ethylamino-9-diethylamino-2-iodobenzo[a]phenothiazinium chloride (2-iodoethyl-NBS, see Figure 7A, where X=I).

The present election is made with traverse. Thee Examiner first errs because he mistakenly concludes that the prolactin enhancers recited in the claims do not share a common utility. The claimed prolactin enhancers all increase the levels of prolactin that circulate in the

blood of a mammal to which they are administered. For this reason, the election requirement should be withdrawn or modified and all of the alleged species of prolactin enhancers should be examined in the present application. The Examiner further errs because he mistakenly concludes that the photosensitizers recited in the claims do not share a common utility or do not share a substantial structural feature disclosed as being essential to that utility. The claimed photosensitizers include the common utility of generating highly reactive and cytotoxic species when irradiated with light of an appropriate wavelength to selectively kill tumor cells. Furthermore, the claimed photosensitizers share a common structural feature that is essential to the stated utility, *i.e.*, they all possess large conjugated ring systems that allow them to absorb light of certain wavelengths to achieve an excited state that then interacts with biomolecules or molecular oxygen to generate reactive species to kill tumor cells. *See, e.g.*, Figures 6A-7E. Furthermore, compounds in the class of benzophenoxazine photosensitizers share a common core having the following structure (where X= oxygen or sulfur):



For these reasons, the requirement to elect a species of photosensitizer should be withdrawn or modified and all of the alleged species of photosensitizers should be examined in the present application.

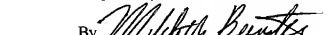
Finally, the Examiner erred in refusing to examine what Applicants regard as their invention, because the claimed invention includes unity of invention. Applicants regard as their invention a method for arresting the growth of or eradicating tumors in a mammal bearing one or more tumors by combined treatment with prolactin rhythm re-setting therapy and photodynamic therapy (PDT). Thus, the instantly claimed invention can be practiced with any prolactin enhancer and any photosensitizing agent. Unity of invention is found in the use of the combination of treatment with a prolactin enhancer and a PDT agent. Thus, it is error for the Examiner to require election of species because the present claims include unity of invention.

In requesting that all species of prolactin enhancers and photosensitizers be examined together, Applicants do not admit that the use of any respective prolactin enhancer or photosensitizer in the instant claims is obvious over the use of any other prolactin enhancer or photosensitizer, or that prior art that might read on one claimed prolactin enhancer or photosensitizer necessarily renders any other claimed prolactin enhancer or photosensitizer obvious. Applicants reserve the right to assert the patentability of each claimed prolactin enhancer and photosensitizer on its own merits.

A prompt and favorable action on the merits of the application is solicited. Should the Examiner believe prosecution would be advanced by conducting an interview with Applicants' representative, the Examiner is requested to contact the undersigned representative. In view of the above response, applicant believes the pending application is in condition for allowance.

Dated: November 27, 2006

Respectfully submitted,

By 

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